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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,888	03/01/2004	Uri Wormser	85189-5800	2632

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PATENT DEPARTMENT
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EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,888	WORMSER, URI	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,13-16,19-26 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,16,19-26,36 and 39-44* is/are rejected.

7)☒ Claim(s) *13-15,37 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Sequence Compliance

1. The newly added peptide labeled SEQ ID NO: 16 is not included in the CRF. See Notice to Comply.

Claim Rejections - 35 USC § 112

2. Applicant's arguments, see pages 9 and 10, filed 8/30/2006, with respect to the rejection under 35 U.S.C. 112, first paragraph, written description requirement, have been fully considered and are persuasive in light of the amendment to the claims. The written description rejection of claims 1-35 has been withdrawn.

3. Applicant's arguments regarding the rejection under 35 U.S.C. 112, first paragraph, enablement requirement, have been fully considered and are found to be persuasive in part.

4. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) the nature of the invention

5. The claims are drawn to pharmaceutical compositions comprising SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 and methods for treating an individual against noxious stimuli and inflammatory processes related to degenerative and autoimmune diseases. The new claims 39 and 40 are

drawn to methods for treating degenerative disorders and tumors by administering SEQ ID NO:9.

(2) the state of the prior art

6. SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 are free of the prior art. The prior art discloses limited examples of derivatives, analogs and homologs of SEQ ID NOs: 1, 2, 4-8, 10-14 and 16.

7. Fibrinopeptide A, an anolog and/or derivative of SEQ ID NOs: 2 and 4 has been shown to prevent excessive allergic reaction (Masuda & Sugiyama, *Peptides*, **2001**, *22*, 1511), have anti-inflammatory properties (Sherer *et* al., Clin. *Exp. Immunol.*, **1980**, *40*, 49) and be useful in the treatment of tumors (Staton *et al.*, US 2004/0039157) and allergic encephalomyelitis, a mouse model of multiple sclerosis (Sherer *et* al., Clin. *Exp. Immunol.*, **1980**, *40*, 49). In addition, histone h2a peptide fragment LRKGNYAERVGAGAP, an analog, homolog and/or derivative of SEQ ID NOs: 1, 5-8, 10 and 13 has been used in the treatment of systemic lupus erythematosus (Datta *et al.*, USPN 6,468,537).

(3) the relative skill of those in the art

8. The relative skill of those in the art is high.

(4) the predictability or unpredictability of the art

9. There is a significant lack of predictability associated with treating autoimmune diseases and chronic degenerative diseases. For example, Citron teaches that current drugs for Alzheimer's disease are safe but of limited benefit to most patents and that the use of anti-inflammatory drugs is promising but in the developmental stages for this disease (*Nat. Neurosci.*, **2002**, *5*, 1055). Rizzello *et al.* teach that Crohn's disease patients are commonly refractive to conventional therapy (*Ailmet Pharmacol. Ther.*, **2002**, *16*, 40). Korczyn & Nussbaum teach that

there is a lack of consensus on how to treat Parkinson's disease during its various stages (*Drugs*, **2002**, *62*, 775). Shuk *et al.* teach that treatments to prevent disability and death from muscular dystrophy are non-existent (*Curr. Op. Neur.*, **2002**, *15*, 563). Coussens & Werb teach that inflammation is a critical component of tumor progression but that related therapies are only in the developmental stage (*Nature*, **420**, *420*, 860). Finally, Ashcroft *et al.* teach that there is substantial variability between and within patients over the course of psoriasis (*J. Clin. Pharm. & Ther.*, **2000**, *25*, 1).

(5) the breadth of the claims

10. The breadth of conditions included within the scope of the claims is significant. Diseases ranging from Altzheimer's Disease to muscular dystrophy to Parkinson' disease to Crohn's Disease are included. Each disease has different patient populations, symptoms, etymologies, mechanisms and treatments.

11. The breadth of compounds included within the scope of the claims is also significant as claims 10 and 36 are drawn to SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 and their analogs, homologs or derivatives. The specification of the instant application defines an analog or derivative as follows: "Active analogs may encompass many variants as are well known in the art, including but not limited to truncations or extensions of amino acids at the amino terminus or carboxy terminus, insertion or deletion of amino acids, N-methylated analogs, and other modifications, provided that these analogs possess anti-inflammatory properties."

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples

12. Given the state of the art at the time the invention was made, one of ordinary skill in the art would not reasonably have been able to predict which of the claimed species, if any, would be useful for treating all diseases and conditions covered by the scope of the claims. Despite the lack of predictability associated with these diseases and the breadth of the claims, the specification only provides evidence that the peptides of claims 10 and 36 can be used to treat thermal- and mustard gas-induced burns.

13. In the response filed 8/30/2006, Applicant has presented additional data suggesting that SEQ ID NO: 13 is effective in art-recognized mouse models for multiple sclerosis (Steinman *et al.*, *Ann. Neurol.*, **2006**, *60*, 12) and arthritis (Myers *et al.*, *Life Sci.*, **1997**, *61*, 1861).

14. Neither the specification or the response offers evidence, guidance or working examples that suggest that SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 could be used to treat inflammation associated with autoimmune diseases or chronic degenerative diseases other than multiple sclerosis and arthritis. The results of the animal models for these diseases are not predicative for all other conditions within the scope of the claims.

15. In the response filed 8/30/2006, Applicant has presented data suggesting that SEQ ID NO:9 is pro-angiogenic, a function that would promote tumor growth rather than suppress tumor growth.

(8) the quantity of experimentation necessary

16. Considering the factors above, the skilled artisan would be burdened with undue experimentation in determining if SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 and their analogs, homologs or derivatives or SEQ ID NO: 9 could be used to treat all autoimmune and degenerative diseases.

17. Claims 16, 19-26 and 39-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of compositions comprising SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 to treat thermal and mustard gas-induced burns, and SEQ ID NOs: 1, 5-8, 10-14 and 16 to treat multiple sclerosis and arthritis, does not reasonably provide enablement for the treatment of inflammation associated with all other autoimmune diseases or chronic degenerative diseases. The rejection of claims 10 and 13-15 under 35 U.S.C. 112, first paragraph, is withdrawn. Claims 1-9, 11, 12 and 27-35 are cancelled rendering the rejection of these claims moot.

18. Claims 11, 12, 29 and 35 are cancelled rendering the rejection of these claims under 35 U.S.C. 112, second paragraph, moot.

Claim Rejections - 35 USC § 102

19. Applicant's arguments filed 8/30/2006 regarding the rejection of claims 1-5, 7-12, 16-30 and 32-35 under 35 U.S.C. 102(a) for being anticipated by Masuda & Sugiyama (*Peptides*, **2001**,*22*, 1511) and under 35 U.S.C. 102(b) for being anticipated by Scherer *et al.* (*Clin. Exp. Immunol.*, **1980**, *40*, 49) have been fully considered but they are not persuasive. Masuda & Sugiyama and Scherer *et al.* teach the administration of the peptide ADSGEGDFLAEGGGV to reduce excessive allergic reaction and to treat allergic encephalomyelitis, respectively. This peptide is not identical to the sequences recited in claims 10 or 36. It is, however, an analog or derivative of SEQ ID NOs: 2 and 4.

20. Compared to the claims sequences SEQ ID NOs: 2 and 4, the peptide taught in the prior art is elongated at the N-terminus, truncated at the C-terminus, and includes the substitution of amino acids at certain positions.

```
Prior art          ADSGEGDFLAEGGGV
SEQ ID NO: 2           DTEFEAAGGGVR
SEQ ID NO: 4         TTDTEFEAAGGGVR
```

The peptide is disclosed in the prior art as having anti-inflammatory properties (see Scherer *et al.*, page 59).

21. The specification of the instant application defines an analog or derivative as follows: "Active analogs may encompass many variants as are well known in the art, including but not limited to truncations or extensions of amino acids at the amino terminus or carboxy terminus; insertion or deletion of amino acids, N-methylated analogs, and other modifications, provided that these analogs possess anti-inflammatory properties." Thus, the peptide taught by Masuda & Sugiyama and Scherer *et al.* is within the scope of claims 10 and 36 which are drawn to analogs, homologs and derivatives of the recited sequences.

22. Claims 10, 16, 19, 22, 24-26, and 36 are rejected under 35 U.S.C. 102(a) for being anticipated by Masuda & Sugiyama. The rejection of claims 20, 21 and 23 under 35 U.S.C. 102 (a) is withdrawn because Masuda & Sugiyama do not teach the treatment of autoimmune or chronic degenerative diseases nor do they teach the administration of the peptide prior to the onset of the allergic reaction. Claims 1-5, 7-9, 11, 12, 17 and 18 are cancelled rendering the rejection of these claims moot.

23. Claims 10, 16, 19-22, 24-26, 36, 41 and 42 are rejected under 35 U.S.C. 102(b) for being anticipated by Scherer *et al.* Allergic encephalomyelitis is a mouse model of multiple sclerosis, a

chronic degenerative and/or autoimmune disease. The rejection of claim 23 under 35 U.S.C. 102 (b) is withdrawn because Scherer *et al.* do not teach the administration of the peptide prior to the onset of the condition. Claims 1-5, 7-9, 11, 12, 17 and 18 are cancelled rendering the rejection of these claims moot.

24. Applicant's arguments filed 8/30/2006 regarding the rejection of claims 1-5, 7-12, 16-30 and 32-35 under 35 U.S.C. 102(e) for being anticipated by Datta *et al.* (U.S. Patent No. 6,468,537) have been fully considered but they are not persuasive. Datta *et al.* teach pharmaceutical compositions for the treatment of systemic lupus erythematosus comprising the peptide LRKGNYAERVGAGAP and methods for administering the same (see SEQ ID NO:9 and claim 1). The peptide taught by Datta *et al.* is not identical to the peptides recited in claims 10 and 36. It is however a derivative, analog and/or homolog of the claimed peptides SEQ ID NO: 1, 5-8, 10 and 13.

25. Compared to the claims sequences SEQ ID NOs: 1, 10 and 13, the peptide taught in the prior art is elongated at the N-terminus, truncated at the C-terminus, and includes the substitution of amino acids at certain positions.

```
Prior art          LRKGNYAERVGAGAP
SEQ ID NO: 10        KGNYAERVG
SEQ ID NO: 1         KGNYAERIA
SEQ ID NO: 13        KGHYAERVG
```

26. Compared to SEQ ID NOs: 5-8, the peptide taught in the prior art is elongated at the N-terminus, truncated at the C-terminus, and includes the substitution of amino acids at certain positions and the incorporation of methylated residues.

```
Prior art          LRK  GNY  AER  VGAGAP
SEQ ID NO: 5         K  GNYMeAER  IA
SEQ ID NO: 6         K  GNY  AERMeIA
```

SEQ ID NO: 7 KMeGNY AER IA
SEQ ID NO: 8 KMeGNY AERMeIA

The peptide is disclosed as having anti-inflammatory properties (see claim 1).

27. The specification of the instant application defines an analog or derivative as follows: "Active analogs may encompass many variants as are well known in the art, including but not limited to truncations or extensions of amino acids at the amino terminus or carboxy terminus, insertion or deletion of amino acids, N-methylated analogs, and other modifications, provided that these analogs possess anti-inflammatory properties." Thus, the peptide taught by Datta *et al.* is within the scope of claims 10 and 36 which are drawn to analogs, homologs and derivatives of the recited sequences.

28. Examiner agrees that Datta *et al.* do not teach or disclose a 9mer peptide comprising the amino acid sequence 36-44 of H2A. However, this argument does not overcome the rejection because the peptide taught by Datta *et al.* is within the scope of claims 10 and 36 for the reasons presented above and is disclosed by Datta *et al.* to be effective at treating systemic lupus erythematosus. Furthermore, the argument that the peptide taught by Datta *et al.* is not effective at treating experimental autoimmune encephalitis in mice or multiple sclerosis in humans is not persuasive because the claims are not limited solely to the treatment of these conditions.

29. Claims 10, 16, 19-22, 24-26, 36, 41 and 42 are rejected under 35 U.S.C. 102(e) for being anticipated by Datta *et al.* The rejection of claim 23 under 35 U.S.C. 102 (e) is withdrawn because Datta *et al.* do not teach the administration of the peptide prior to the onset of the condition. Claims 1-5, 7-9, 11, 12, 17 and 18 are cancelled rendering the rejection of these claims moot.

30. Applicant's arguments filed 8/30/2006 regarding the rejection of claims 1-5, 7-12, 16-30 and 32-35 under 35 U.S.C. 102(e) for being anticipated by Stanton *et al.* (U.S. Publication No. 2004/0039157) have been fully considered but they are not persuasive. Stanton *et al.* teach pharmaceutical compositions for the treatment of tumors comprising the peptide ADSGEGDFLAEGGGVRGPRVVERH and methods for administering the same. The peptide taught by Stanton *et al.* is not identical to the peptides recited in claims 10 and 36. It is however a derivative, analog and/or homolog of the claimed peptides SEQ ID NOs: 2 and 4.

31. Compared to the claims sequences SEQ ID NOs: 2 and 4, the peptide taught in the prior art is elongated at the N-terminus, truncated at the C-terminus, and includes the substitution of amino acids at certain positions.

```
Prior art          ADSGEGDFLAEGGGVRGPRVVERH
SEQ ID NO: 2           DTEFEAAGGGVR
SEQ ID NO: 4         TTDTEFEAAGGGVR
```

32. The specification of the instant application defines an analog or derivative as follows: "Active analogs may encompass many variants as are well known in the art, including but not limited to truncations or extensions of amino acids at the amino terminus or carboxy terminus, insertion or deletion of amino acids, N-methylated analogs, and other modifications, provided that these analogs possess anti-inflammatory properties." Thus, the peptide taught by Stanton *et al.* is within the scope of claims 10 and 36 which are drawn to analogs, homologs and derivatives of the recited sequences.

33. The argument that Stanton *et al.* disclose that a shorter peptide is not effective at treating tumors is not persuasive because the peptide taught by Stanton *et al.* is within the scope of claims

10 and 36 for the reasons presented above and is disclosed by Stanton *et al.* to be effective at treating tumors.

34. Claims 10, 16, 20-22, 24-26, 36, 43 and 44 are rejected under 35 U.S.C. 102(e) for being anticipated by Stanton *et al.* The rejection of claims 19 and 23 under 35 U.S.C. 102 (e) is withdrawn because Stanton *et al.* do not teach the treatment of noxious stimuli or the administration of the peptide prior to the onset of the condition. Claims 1-5, 7-9, 11, 12, 17 and 18 are cancelled rendering the rejection of these claims moot.

35. The rejections under 35 U.S.C. 102 (a), (b) and (e) could be overcome by deleting the phrase "and their analogs, homologs or derivatives," from claims 10 and 36.

Double Patenting

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

37. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

38. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

39. Claims 10, 16, 21 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 11-13 of copending application No. 11/527,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope. Specifically, SEQ ID NOs: 1, 5 and 10-13 which are in the scope of claims 36 and 10 also fall within the scope of the claims 1 and 11 respectively, of copending application No. 11/527,162. For the same reason, the methods of claim 16 and 21 overlap in scope with the methods of claims 11-13 of copending application No. 11/527,162. Claim 36 also overlaps in scope with claim 2 of copending application No. 11/527,162 because SEQ ID NOs: 12 ad 13 of the instant application are identical to SEQ ID NOs: 30 and 31, respectively of copending application No. 11/527,162 and because SEQ ID NOs: 4-13, 17 and 34-38 of copending application No. 11/527,162 are derivatives of SEQ ID NO: 13 of the instant application. Finally, claim 36 also overlaps in scope with claims 3 and 4 of copending application No. 11/527,162 because derivatives of SEQ ID NOs: 1, 5 and 10-13 would fall within the scope of the genus of claims 3 and 4 of copending application No. 11/527,162.

40. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

41. Claims 13-15, 37 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

42. SEQ ID NOs: 1, 2, 4-8, 10-14 and 16 are free of the prior art.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

44. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

45. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

46. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

47. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.
Patent Examiner
Art Unit 1654

cmb

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600

Notice to Comply	Application No. 10/790,888	Applicant(s) WORMSER, URI	
	Examiner Christina Marchetti Bradley	Art Unit 1654	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☒ 7. Other: SEQ ID NO:16 is not included in the sequence listing

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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